DATA EVALUATION RECORD

EPA Primary Reviewer: Ibrahim S. Barsoum, Ph.D. ISB
EPA Secondary Reviewer: John L. Kough, Ph.D. JLK

STUDY TYPE:	Product Identity and Composition (OCSPP 885.1100) Manufacturing Process (OCSPP 885.1200) Discussion of Formation of Unintentional Ingredients (OCSPP 885.1300) Analysis of Samples (OCSPP 885.1400) Certification of Limits (OCSPP 885.1500) Enforcement Analytical Method (OCSPP 830.1800) Physical and Chemical Characteristics (OCSPP 830.6302-830.7950)
MRID NO:	48969301 & 48969302
DECISION NO:	478892
DP BARCODE:	418701
TEST MATERIAL:	*Bacillus subtilis* strain IAB/BS03 Technical Powder
PROJECT STUDY NO:	Not provided
SPONSOR:	IAB, S.L.,
TESTING FACILITY:	IAB, S.L., 46113 Moncada (Valencia), SPAIN
TITLE OF REPORT:	Product Chemistry for *Bacillus subtilis strain IAB/BS03* Technical
AUTHOR:	Amy P. Roberts, TSI, Inc.
STUDY COMPLETED:	May 7, 2013
CONFIDENTIALITY CLAIMS:	Confidential information is contained in a confidential appendix.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The study does not meet the requirements of 40 CFR Part 160.
CONCLUSION:	*Bacillus subtilis strain IAB/BS03* Technical (EPA Reg. No. 89615-R) is a technical grade active ingredient/ manufacturing use product to be incorporated into end use products. *Bacillus subtilis* is a rod-shaped, gram-positive, aerobic, motile bacterium which is ubiquitous in nature and has been recovered from water, soil, air and decomposing plant residue. *Bacillus subtilis* strain IAB/BS03 is antagonistic to fungal plant pathogens through nutrient competition, site exclusion and colonization. Acceptable product identity, manufacturing procedure, detection of undesired contaminants, analysis of samples, and chemical and physical characteristics were submitted.
CLASSIFICATION:	**ACCEPTABLE**

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Test Material: *Bacillus subtilis strain IAB/BS03* Technical (a.i., 100.0% w/w *BACILLUS SUBTILIS STRAIN IAB/BS03*)

PRODUCT IDENTITY AND COMPOSITION: Taxonomic Identification:

- **Domain**: Bacteria
- **Phylum**: Firmicutes
- **Class**: Bacilli
- **Order**: Bacillales
- **Family**: Bacillaceae
- **Genus**: *Bacillus*
- **Specific descriptor**: *subtilis*
- **Scientific name**: - *Bacillus subtilis*

Alternatives, synonyms, superseded names associated with the microorganism:
Vibrio subtilis
Strain origin: *Bacillus subtilis* strain IAB/BS03 was isolated from the rhizosphere of cucurbits in Valencia, Spain.

Natural occurrence of the microorganism: *Bacillus subtilis* is a naturally occurring bacteria found in agricultural soils worldwide. *Bacillus subtilis* is a rod-shaped, gram-positive, aerobic, motile bacterium which is ubiquitous in nature and has been recovered from water, soil, air and decomposing plant residue.

Mode of action: *Bacillus subtilis* strain IAB/BS03 is antagonistic to fungal plant pathogens through nutrient competition, site exclusion and colonization.
Pest host range: *Bacillus subtilis* strain IAB/BS03 controls foliar fungal pathogens. *B. subtilis* is not characterized by a distinct host specificity since growth is not dependent upon a host but upon supply with decomposable organic matter. Moreover the endospore is prevalent in all environmental compartments and *B. subtilis* is not geographically restricted.

Life cycle: All spore-formers, including members of the Genus *Bacillus*, undergo a cycle consisting of several discernible phases: germination, outgrowth, multiplication and sporulation. The primary cell formed at the end of outgrowth can, under some unfavorable conditions, such as insufficient nutrients, divide asymmetrically and proceed directly to sporulation. Under favorable conditions, such as sufficient nutrients. The bacterium can divide symmetrically and proceed through many divisions before sporulation. The endospore plays a dominant role in the biology and the life-cycle of *B. subtilis* and relatives. The global distribution of *Bacillus* spp. may largely be derived from the endospore-forming capability. Basically the endospore is the most heat tolerant bacterial life-form, enduring temperatures >80 °C or even >100 °C.

Location in an internationally recognized culture collection: *Bacillus subtilis* strain IAB/BS03 is on deposit at the internationally recognized (Budapest Treaty) Colección Española de Cultivos Tipo (CECT) as CECT No. 7254.

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Pages 3-4 *Manufacturing process information may be entitled to confidential treatment*

Physical/Chemical Properties for *Bacillus subtilis* strain IAB/BS03 Technical Powder.

OCSPP Guideline Name	Observation
Color	White
Physical state	Solid powder
Odor	Slight fermentation odor
Stability to normal/elevated temps, metals & metal ions	Stable at normal temperatures for up to two years. Stable at elevated temperatures as endospores of *Bacillus subtilis* are heat tolerant. Expected to be stable in contact with metal and metal ions.
Storage stability	Data on the TGAI/MUP is not available, as it is formulated immediately into end-use products during the manufacturing process (continuous process). Formulated products are stable for up to 3 months at RT and 6 months at 8° C.
Miscibility	*Not applicable per 40 CFR 158.2120(d)(2) – TGAI/MUP is not an emulsifiable liquid and is not diluted with petroleum solvents.*
Corrosion characteristics	Data on the TGAI/MUP is not available, as it is formulated immediately into end-use products during the manufacturing process (continuous process). No degradation seen in packaging integrity during a two-year storage stability study at ambient temperatures.
pH	5.0 – 9.0
Viscosity	*Not applicable per 40 CFR 158.2120(d)(4) – TGAI/MUP is not a liquid.*
Density/relative density/bulk density	0.74 g/ml

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